REPORT DOCUMENTATION PAGE

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OMB No. 0704-0188

PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ORGANIZATION.

1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
15/12/2016	final	23/11/10-14/12/2016

4. TITLE AND SUBTITLE
Cinnamon Bark, Water-Soluble Cinnamon Extract, and Metformin as Initial Treatment for Type 2 Diabetes Mellitus: A Randomized, Controlled Trial.

5a. CONTRACT NUMBER

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Paul Crawford, MD

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Clinical Investigation Program
Mike O'Callaghan Federal Medical Center
4700 Las Vegas Blvd North
Nellis AFB, NV 89191

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
Clinical Investigation Program
Mike O'Callaghan Federal Medical Center
4700 Las Vegas Blvd North
Nellis AFB, NV 89191

10. SPONSOR/MONITOR'S ACRONYM(S)
FWH20110004H

11. SPONSOR/MONITOR'S REPORT NUMBER(S)
FWH20110004H

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release; distribution is unlimited.

13. SUPPLEMENTARY NOTES

14. ABSTRACT
No results are available. The study proved unworkable due to the lack of subject recruitment and is being closed.

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			Jill Clark
U	U	U	UU		19b. TELEPHONE NUMBER *(Include area code)* (702) 653-3298

Reset

Standard Form 298 (Rev. 8/98)
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59th Medical Wing (59th MDW)
Institutional Review Board (IRB)
59th Clinical Research Division/SGVUS/(210) 292-7143
2200 Bergquist Dr, Bldg 4430, Lackland AFB, TX 78236-9908
Federal Wide Assurance #FWA00001750 and DoD Assurance #50007

14 Dec 16

FINAL REPORT ACKNOWLEDGEMENT:

Acknowledgement Date: 14 Dec 16

Principal Investigator: Col Paul Crawford/NELLIS AFB

IRB Reference Number: FWH20110004H

Protocol Title: "Cinnamon Bark, Water-Soluble Cinnamon Extract, and Metformin as Initial Treatment for Type 2 Diabetes Mellitus: A Randomized, Controlled Trial."

1. Your Final Report submitted 9 Dec 16 for the study referenced above, was reviewed by the IRB Chairperson or designated reviewer, acknowledged on 14 Dec 16 and will be reported to the IRB for information. Final Reports are forwarded to SGE-C for their information.

This study was due to expire 26 Jul 17.
This study is **now closed** as of **14 Dec 16**.

Documents Reviewed: Final Report, Form A-1 Principal Investigator's Signature Sheet (Reason Closed: U-Unworkable) FOLLOW-UP CLOSED

2. **Please note: By submitting your final report you indicated that you and your research team will no longer have access to identifiable information for the purposes of this research study. Best practice would suggest that you have already, returned any unused test articles or funding, forwarded all blood or tissues samples (if any) as appropriate for your protocol, and contacted all of your research team, all engaged institutions, clinics, supporting organizations, funding agencies, etc. regarding the cessation of all research activity on this study.

3. IAW AFI 40-402 Inactivation of this study will be reported to AFMSA/SGE-C, and documented in a subsequent IRB minutes to the **24 Jan 17** IRB Meeting.

4. If you have any questions, please contact Norma Ibarra at (210) 292-5819 or norma.a.ibarra3.ctr@mail.mil. Please include your project title and reference number in all correspondence or inquiries.

NORMA IBARRA
Clinical Research Coordinator
SGVUS (Protocol Support)
(210) 292-5819

FINAL REPORT – NON-EXEMPT HUMAN RESEARCH

Title:	Cinnamon bark, water-soluble cinnamon extract, and Metformin as initial treatment for Type 2 diabetes mellitus: A randomized, controlled trial.
IRB #:	FWH20110004H

Principal Investigator (PI)	Rank / Civ Rating	Branch	AD/DoD Civ/ Ctr/Civilian	Dept/Base	Phone #	E-mail
Paul Crawford, MD	COL	USAF	AD	FMR/Nellis	(702) 653-3298	Paul.crawford@us.af.mil

Purpose of Study:

The purpose of this study is to assess whether Cinnamon bark or water-soluble cinnamon is an effective nutraceutical for the initial treatment of diabetes when compared to standard therapy of Metformin.

Results from Study:

No results are available. The study proved unworkable due to the lack of subject recruitment and is being closed.

How May your Findings Benefit the Air Force?

No results are available. The study proved unworkable due to the lack of subject recruitment and is being closed.

Reason for Closure:

☐	Objectives of the study were met
☐	Study is no longer necessary (outmoded, outdated, science has changed)
☐	Closed by sponsor
☑	Unworkable (explain in problems section)
☐	Withdrawn
☐	Other:

Consent Process:		
Used a Request for Waiver of Written ICD and a Request for Waiver of HIPAA Authorization.	☐ Yes	☑ No
Each participant was recruited in accordance with the recruitment plan approved by the IRB.	☑ Yes	☐ No
Each participant was consented in accordance with the consent process approved by the IRB.	☑ Yes	☐ No
Each participant was given a copy of the signed, date-stamped informed consent document.	☑ Yes	☐ No
As the PI, I have retained a copy of each participant's signed, dated informed consent document.	☑ Yes	☐ No

Status of Subjects:		
Subject's participation is as expected.		
The study has the potential for long term side effects:	☐ Yes	☑ No
The study implanted a device into the subject:	☐ Yes	☑ No

Number of Subjects Entered into the Study:

	# Approved to Enroll	# Enrolled Since Last Report	Withdrawals To-Date	TOTAL Enrolled To-Date
Number of Subjects at MOFMC	309	2	3	25

Office of Research Protocol Support Use Only:

Who Signed?	☐ PI		☐ Co-PI		☐ Auth AI		
Received on:		**Initials:**		**Report Expiration Date:**		**Scheduled for IRB:**	

Summary of Patient Withdrawals from the Study:			
# of Withdrawals Since Last Report:	1	TOTAL # of Withdrawals To-Date:	3

Date of Withdrawal	Withdrew Due to Screening Failure?	Reason for Patient Withdrawal:
08/18/15	NO	012: Elevated liver enzymes suggest potential alcohol abuse
05/20/16	NO	019: Side effects from Metformin (Diarrhea)
07/14/16	NO	020: Experience leg swelling

Summary of Unanticipated Problems Involving Risk to Subjects or Others (UPIRSO) Events: NONE

Summary of Serious Adverse Events (SAE): NONE

Summary of Protocol Deviations:			
# of Deviations Since Last Report:	0	TOTAL # of Deviations To-Date:	1

Date Deviation Reported	Local or External?	Description of Protocol Deviation and Action Taken:
07/07/15	Local	Subject 010 subject signed an expired copy of the Informed consent document. The Informed Consent expired on 9/24/14 and the subject signed it on 9/25/14.

Summary of Complaints About the Study: NONE

Amendments/Changes to Protocol, Informed Consent, or Investigator's Brochure:			
# of Amendments Since Last Report:		TOTAL # of Amendments To-Date:	

Amendment #	Date Approved	Summary of Changes:
1	22 Mar 11	SGE-C requested changes to the protocol
2	6 Apr 11	SGE-C requested changes to the protocol and ICD
3	28 Jun 11	Changes to the protocol and ICD. Added an AI, 90 day study calendar and diet and exercise questionnaire.
4	24 Jan 12	Research protocol, ICD, external support appendix and investigational new drug appendix (SGEC and FDA IND recommended changes, PI Letter dated 15 Dec 2011)
5	24 Apr 12	Added changes to the protocol and ICD in response to FDA IND suggestion. Added exclusion criteria for liver disease, alcoholism and NYHA Class III and IV congestive heart failure, added one week lab visit, fasting comprehensive metabolic panel, self-monitoring blood glucose statement and added risk for hypoglycemic episodes.
6	18 Dec 12	Add and remove an AI
7	8 Jan 13	Change contractor information for an RA
8	19 Feb 13	Update advertisement flyer
9	4 Apr 13	Add side effects document to be given to subjects at time of medication dispensing.
10	25 Feb 14	Add 2 AI's 2 RA's 2 Research monitors, remove 2 AIs and changes to the protocol and ICD
11	9 Jun 14	Remove 3 research team members, add one member, minor updates to the protocol, Form A2 and HIPAA
12	5 Aug 2014	Remove from the protocol and form A2: Tom Harris, Samantha Choudhury, and add Lisa Stammers. Also in the protocol to remove the line stating the patients will bring in remaining drug to determine adherence rate since we are not doing pill counts.
13	28 Oct 2014	Removal of an AI and revision of inclusion criteria.
14	19 Nov 15	Requesting personnel changes and changes to study diary and adding a new research monitor

15	16 Nov 15	Requesting to make changes in the protocol and ICD
16	30 June 16	Requesting to add personnel, to make changes to the protocol, to make changes in the ICD, to make changes in the RAND 36 Item Questionnaire and updating HIPAA

Status of Resources:		
All resources have been exhausted.		
The study used a drug that had an IND:	☑ Yes	☐ No
The drugs were inventoried and disposed of in accordance in hospital policy.		
The study used a device that had an IDE:	☐ Yes	☑ No

Describe the local investigator's ongoing plan to protect the confidentiality of the research data:
The research documents will be stored and destroyed in compliance with WHASC guidelines.

Describe the local investigator's plan to store the research records:
The PI will keep an electronic copy of the informed consent documents and HIPAAs for at least 3 years after the study is complete. Once the study is closed, the WHASC IRB will be sent a digital copy for indefinite archiving.

Publications and Presentations: NONE

Exceptional Achievements: NONE

CC: Maj David Moss, Research Monitor (Primary), Maj Tristan Sevdy (Alternate)

Attachments:
1. Adverse Events Tracking Log
2. SAFE File Exchange of signed Informed Consent Documents/HIPAAs
3. Form A-1, Multi-Purpose Signature Sheet